

OCT 25 2010

Section 5: 510(k) Summary

The following information is provided as required by 21 CFR § 807.87 for the Cranial LOOP Cranial Bone Fixation System (Cranial LOOP) 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

Sponsor: Neos Surgery S.L.
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Barcelona, Spain

Contact: Marcos Velez-Duran
M Squared Associates, Inc.
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Date of Submission: April 30, 2010

Proprietary Name: Cranial LOOP Cranial Bone Fixation System

Common Name: cranial fixation device

Regulatory Class: 882.5250 Burr hole cover, 882.5330 Preformed nonalterable cranioplasty plate

Product Codes: GXR, GXN

Predicate Device(s): INVISx-K010361, CranioFix- K040080, CranioFix Titanium-K972332

Device Description: The Cranial LOOP Cranial Bone Fixation System is a biocompatible, postoperative cranial bone fixation system that fixes the bone flap to the skull, without any specific surgical instrument for its handling or implantation. It is provided sterile, for single use.

Intended Use: The Cranial Loop Cranial Bone Fixation System is a long-term implantable device indicated for post-craniotomy bone flap fixation.

Discussion of performance testing: Mechanical and various performance testing confirms the Cranial LOOP Cranial Bone Fixation System performs as intended and is substantially equivalent to the predicate devices.

Technological comparison: The claim of substantial equivalence of the Cranial Loop to the predicate devices is based on the comparison of the intended use, product technical characteristics, performance characteristics and product handling.



Food and Drug Administration
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Silver Spring, MD 20993-0002

Neos Surgery, S.L.
% Mr. Marcos Velez-Duran
President
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901 King Street, Suite 200
Alexandria, VA 22314

OCT 25 2010

Re: K101235

Trade/Device Name: Cranial LOOP Cranial Bone Fixation System
Regulation Number: 21 CFR 882.5250
Regulation Name: Burr Hole Cover
Regulatory Class: Class II
Product Code: GXR
Dated: September 29, 2010
Received: October 1, 2010

Dear Mr. Velez-Duran:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

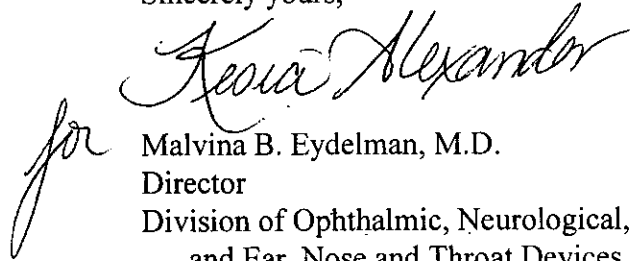
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Indications for Use Statement

OCT 25 2010

510(k) Number: To be assigned K101235

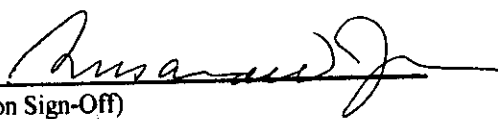
Device Name: Cranial LOOP Cranial Bone Fixation System

Indications for Use: The Cranial LOOP Cranial Bone Fixation System is a long-term implantable device indicated for post-craniotomy bone flap fixation.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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